

1. Defendant TIMOTHY SUTTON has been licensed to practice medicine in the state of Ohio since January 9, 2019.
2. Defendant was employed by, among other entities, Telemedicine Company 1 and Telemedicine Company 2. Telemedicine Company 1 purported to provide telemedicine services, including direct contact with licensed medical practitioners (“practitioners”) via telephone and video. Telemedicine Company 2 was a telemedicine company that purported to provide telemedicine services in addition to providing telehealth staffing solutions to organizations in need. Telemedicine Companies 1 and 2 (the “Telemedicine Companies”) purported to service the cancer genetic testing (“CGx”) and durable medical equipment (“DME”) industries.

B. CGx Testing and DME

3. Because the orders for DME braces and CGx testing required the signature of a practitioner who was credentialed with Medicare, the Telemedicine Companies paid practitioners like Defendant to review and sign pre-completed orders for DME braces and CGx testing.

4. The documents for DME brace and CGx testing orders provided to the practitioners by the Telemedicine Companies consisted of the following: (1) a medical examination note addressing the beneficiary's reported complaint, subjective notes, objective notes purportedly by the "treating physician," assessment notes including the diagnosis codes, and the plan notes and treatment goals; (2) a letter of medical necessity; and (3) a detailed written order for the brace(s) or test (s). Often there were multiple orders for the same beneficiary included in the same review package.

5. The Telemedicine Companies provided practitioners, including Defendant, access to the review package for the DME brace or CGx testing orders in a web site portal. The Telemedicine Companies notified Defendant that records and orders were pending for his review and execution.

6. Once the practitioners approved the DME brace or CGx testing orders, the Telemedicine Companies either forwarded the orders to companies controlled by the owners of the Telemedicine Companies or sold the orders to companies or persons who owned, managed, and/or controlled Medicare-enrolled DME supply or laboratory companies for submission to Medicare and other federal health benefit programs.

The Medicare Program

7. The Medicare Program (“Medicare”) was a federal health care benefit program that provided items and services to individuals who were (a) age 65 or older, (b) had certain disabilities, or (c) had end-stage renal disease. Individuals who received Medicare benefits were called “beneficiaries.”

8. Medicare was a “health care benefit program,” as defined by Title 18, United States Code, Section 24(b), in that it was a public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service, for which payment may be made under the plan or contract.

9. The Centers for Medicare and Medicaid Services (“CMS”), which was an agency of the United States Department of Health and Human Services (“HHS”), administered Medicare.

10. To receive Medicare reimbursement for benefits, items or services performed or provided to beneficiaries, practitioners had to apply for and execute a written provider agreement, known as a CMS Form 855.

11. Defendant became an approved Medicare provider on July 19, 2016. As part of his enrollment, Defendant certified that he agreed “to abide by the Medicare laws, regulations and program instructions” and acknowledged that “the Medicare laws, regulations, and program instructions are available through” the assigned Medicare contractor. Practitioners enrolled with Medicare had access to Medicare manuals, service bulletins, and local coverage determinations

and policies describing Medicare coverage requirements for various services and items, including DME braces.

12. Defendant also certified that he “will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.” The Medicare enrollment application signed by Defendant set forth various criminal offenses related to participation in Medicare and the delivery of and payment for health care benefits, items, or services. Specifically, the Enrollment Application addressed Title 18, United States Code, Section 1035(a) which authorized criminal penalties against individuals:

in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statements or misrepresentations, or makes or uses any materially false[,] fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items or services.

13. Medicare was made up of several component “parts” that covered different items and services. Medicare Part B covered, among other items and services, outpatient care and supplies, including orthotic devices “braces”, referred to as DME. Medicare Part B covered claims submitted for DME, including off-the-shelf knee braces, suspension sleeves, back braces, shoulder braces, ankle braces, and wrist braces, if the DME was medically reasonable and necessary for the treatment of the beneficiary’s illness or injury and prescribed by a licensed medical practitioner. 42 U.S.C. § 1395y(a)(1)(A).

14. To help administer Medicare, CMS contracted with private insurance companies called “Medicare Administrative Contractors” or “MACs.” MACs performed many functions, such as enrolling DME suppliers into the Medicare program and processing Medicare claims.

DME

15. Section 1847(a)(2) of the Social Security Act defined Off-The-Shelf (“OTS”) orthotics as those orthotics described in Section 1861(s)(9) of the Act for which payment would otherwise be made under Section 1843(h) of the Act, which required minimal self-adjustment for appropriate use and did not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Orthotics that were paid for under Section 1834(h) of the Act and were described in Section 1861(s)(9) of the Act were leg, arm, back, and neck braces. The Medicare Benefit Policy Manual (Publication 100-2), Chapter 15, Section 130 provided the longstanding Medicare definition of “braces.” Braces were defined in this section as “rigid or semi-rigid devices which were used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.”

16. Under Medicare Part B, beneficiaries could only receive Medicare-covered DME braces from “suppliers” that were enrolled in Medicare.

17. DME supply companies submitted claims for payment of DME braces to MACs for beneficiaries in Ohio. Pursuant to Medicare requirements, DME supply companies had to submit certain information relating to the beneficiary receiving the DME braces, including the following:

- a. the type of service provided, identified by an “HCPCS” code (meaning “Healthcare Common Procedure Coding System”);
- b. the date of service or supply;
- c. the referring physician’s National Provider Identifier (“NPI”);
- d. the charge for the service;
- e. beneficiary’s diagnosis;

- f. the NPI for the DME entity seeking reimbursement; and
- g. certification by the DME provider that the DME braces are medically necessary.

18. Further, before submitting a claim for a DME brace to a MAC, a DME supply company was required to have on file the following:

- a. written documentation of a verbal order or a preliminary written order from a treating physician or qualified medical practitioner;
- b. a detailed written order from the treating physician or qualified medical practitioner;
- c. information from the treating physician or qualified medical practitioner concerning the beneficiary's diagnosis;
- d. any information required for the use of specific modifiers;
- e. a beneficiary's written assignment of benefits; and
- f. proof of delivery of the DME brace to the beneficiary.

CGx Testing

19. Cancer Genetic Testing ("CGx") was a type of genetic test administered for patients with a genetic predisposition to cancer. Medicare issued National Coverage Determination 90.2, effective March 16, 2018, which stated: "Patients with cancer can have recurrent, relapsed, refractory, metastatic, and/or advanced stages III or IV of cancer. Clinical studies show that genetic variations in a patient's cancer can, in concert with clinical factors, predict how each individual respond to specific treatments." Accordingly, Medicare only reimbursed genetic testing for beneficiaries with a diagnosis of cancer when ordered by a treating physician for the purpose of determining the proper course of treatment for the beneficiary.

20. Title XVIII of the Social Security Act (SSA) § 1862(a)(1)(A), stated that no Medicare payment shall be made for items or services that "are not reasonable and necessary for

the diagnosis or treatment of illness or injury or to improve the functioning of malformed body member.” Title 42, Code of Federal Regulations § 410.32 provides:

All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the result in the management of the beneficiary’s specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

21. Accordingly, Medicare did not reimburse for genetic screening tests performed simply to determine the likelihood a beneficiary will or will not develop cancer in the future. Rather, Medicare paid only for genetic screening tests performed to aid in the treatment of a beneficiary with a personal diagnosis of cancer. Medicare reimbursed for the test at rates varying from approximately a few hundred dollars to over \$6,000.

SCHEME TO DEFRAUD

22. It was part of the scheme to defraud that at various times Defendant:
- a. signed and caused to be signed false statements concerning patients;
 - b. issued orders for medically unnecessary DME and CGx testing; and
 - c. caused the submission of billing to Medicare for medically unnecessary DME and CGx testing.

COUNT 1

(Health Care Fraud, 18 U.S.C. §§ 1347 and 2)

The Grand Jury charges:

23. The allegations of paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as if fully set forth herein.

24. From on or about January 26, 2018, through on or about October 21, 2020, Defendant TIMOTHY SUTTON did knowingly and willfully execute, and attempt to execute,

the above-described scheme and artifice to defraud and to obtain money from federal health care benefit programs by means of false and fraudulent pretenses, representations, and promises.

25. From on or about January 26, 2018 to on or about October 21, 2020, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendant knowingly and willfully executed, and attempted to execute, a scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is Medicare, and to obtain by means of the false and fraudulent pretenses, representations, described herein, money and property owned by, and under the custody and control of Medicare, in connection with the delivery of and payment for health care benefits, items and services, in violation of Title 18, United States Code, Sections 1347 and 2.

COUNTS 2-8

(False Statement Relating to Health Care Matters, 18 U.S.C. §§ 1035 and 2)

The Grand Jury further charges:

26. The allegations of paragraphs 1 through 21 of this Indictment are re-alleged and incorporated by reference as if fully set forth herein.

27. On or about the dates listed below, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendant TIMOTHY SUTTON, in a matter involving a health care benefit program, did knowingly and willfully make and use any materially false writing and document knowing the same to contain any materially false, fictitious, and fraudulent statement and entry, in connection with the delivery of and payment for health care benefits, items and services; to wit, Defendant made and caused to be made and submitted false statements in the patient records for the following patients in connection with claims for reimbursement on the dates indicated, each patient record constituting a separate count:

Count	Date	Beneficiary	False Statement
2	1/21/2019	G.H.	Patient has a Beighton Score of 4 and is unable to touch the floor with the palm of their hands without bending their knee. Pivot shift test is positive.
3	8/24/2019	J.J.	I have ordered a pharmacogenetics diagnostic test to assist me in making patient-specific clinical decisions regarding the medical management.
4	8/14/2019	J.J.	The purpose of this letter is to document medical necessity for hereditary cancer genetic testing for the patient so that I will receive the test results in order to pursue care for the patient and to request full coverage of the patient's DNA-based hereditary cancer diagnostic test.
5	11/8/2019	I.L.	The patient has a Beighton Score of 4 and is unable to touch the floor with the palm of their hands without bending their knee(s). Laxity Pivot Test is positive. Pivot shift test is positive.
6	11/8/2019	L.C.	The patient has a Beighton Score of 4 and is unable to touch the floor with the palm of their hands without bending their knee(s). Laxity Pivot Test is positive. Pivot shift test is positive.
7	11/10/2019	E.C.	The patient has a Beighton Score of 4 and is unable to touch the floor with the palm of their hands without bending their knee(s). Pivot shift test is positive.
8	4/5/2018	D.R.	I, Timothy Sutton, verify and confirm this order for the above named patient, and certify that I have personally performed the examination and assessment of the patient for the prescribed treatment and device and verify that it is reasonably and medically necessary, according to accepted standards of medical practice within the community, for this patient's medical condition.

All in violation of Title 18, United States Code, Sections 1035 and 2.

A TRUE BILL.

Original document - Signatures on file with the Clerk of Courts, pursuant to the E-Government Act of 2002.